

K073028

Section B



MAR - 7 2008

510 (k) Summary

**Venowave Inc.
Venowave VW5 family
(including VW5-6; VW5-10; VW5-20; VW5-30)**

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Date Prepared: October, 2007

Trade Name: Venowave VW5
Common Name: Wave-generating device
Classification Name: Sleeve, Limb, Compressible
Classification: Class II, Product Code JOW;
Regulation No. 870.5800
Panel: Cardiovascular

Predicate Device: Medical Compression Systems (DBN) Ltd.'s
ActiveCare++ System approved for marketing under K060146.

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Device Description:

The Venowave VW5 is a series of compact, battery-operated peristaltic pumps that generate a wave-form motion, and when worn below the knee strapped firmly to the calf, result in compression of the calf and consequently an increased upward volumetric displacement of venous and lymph fluid. Each of the models within the family (VW5-6; VW5-10; VW5-20; and VW5-30) is distinguished by the maximum number of times the wave plate cycles each minute (6, 10, 20 and 30 cycles/minute respectively). Each model is also capable of operating at two speeds. Clinical preference to choose a specific frequency of motion for each specific patient based upon that patient's clinical symptoms, severity of disease, and perceived compliance with treatment has been the motivation for creating each model within the series. The optimum choice of model for each patient is the slowest device that achieves the desired therapeutic objective. The slower the device is, the quieter the operation and the longer the battery and mechanical life of the unit. Each model, however, may in fact be used interchangeably to treat patients suffering from a class of diseases that result from chronic venous insufficiency.

The Venowave VW5 weighs about 260g, and has dimensions measuring roughly 190mm x 75mm x 30mm enabling one to wear it under loose clothing. It is designed to be packaged and sold as a prescription-only assembled device.

The Venowave generates a mechanical wave which starts at the lower pivot point and travels to the upper pivot point, a distance of 14cm (wavelength) traveled for each cycle of the crank. The swept volume or volume of blood or lymph fluid displaced upwards for each cycle is the product of the wavelength (14cm), the width of the wave sheet (7.5cm) and the depth of the wave (0.95cm) or approximately 0.1 L/cycle. Operating by way of a single rechargeable 1.5 V NiMh AA battery, this single-patient use device enables the user to receive treatment anywhere, while remaining active.

Intended Use:

The Venowave VW5 series of devices are prescriptive and induce improved vascular and lymphatic flow of the lower limbs. Very similar to the predicate device, the Venowave VW5 series of devices are intended to treat the following:

- Management of the symptoms of post thrombotic syndrome (PTS)
- Prevention of deep vein thrombosis, (DVT)
- Prevention of primary thrombosis
- Treatment of lymphedema
- Diminishing post-operative pain and swelling
- Treatment of leg swelling due to vascular insufficiency
- Treatment of varicose veins
- Treatment of chronic venous insufficiency
- Enhancing blood circulation
- Treatment of intermittent claudication



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Differences in intended indications of use are three-fold:

1. The predicate device is indicated for reducing wound healing time and treatment of ulcerative legs, whereas the Venowave, due to its mechanical pressure applied on the muscle, may exacerbate healing of open wounds and hence is contra-indicated for these conditions; and
2. The Venowave has been clinically evaluated in patients with post thrombotic syndrome and has been found to be effective in the management of their symptoms (see Appendix 6). In addition, due to its discreet profile, relative lightweight, and ability to use while the patient remains active, it would offer a non-invasive therapeutic option for patients with varicose veins, another symptom of chronic venous insufficiency.
3. By improving venous return in the calf and thereby reducing venous capillary pressure, symptoms of intermittent arterial claudication could be alleviated as arterial flow in the extremity is improved.

Contraindications:

The Venowave VW5 venous pump should not be used with patients with open leg ulcers or other leg wounds.

Performance Standards:

No performance standards have been established for devices such as the Venowave VW5 or the predicate device under Section 514 of the Food, Drug and Cosmetic Act.

Performance Data & Substantial Equivalence:

The Venowave VW5 family of venous pumps is substantially equivalent in virtually all aspects to the commercially available predicate device granted market approval (K060146) on March 8, 2006 including performance characteristics, application, and indications of use. Additionally, the technological characteristics, mode of operation, source of power, target populations and intended use of the Venowave VW5 relative to the predicate device are very similar and, in the estimation of the manufacturer, do not raise new questions of safety and effectiveness relative to the predicate device.

The principle difference between the two devices is quite simple: the Venowave VW5 deploys a peristaltic pumping action using a mechanical plate to compress the muscles of the calf thereby increasing upward venous and lymphatic flow. The predicate device, namely the ActiveCare ++ System, uses a pneumatic cuff which relies on compressed air within a sleeve around the calf to intermittently compress the muscles of the calf and generate increased upward venous and lymph flow. The predicate device also uses a larger battery (7.2V) to affect its intended results relative to that of the Venowave VW5



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(1.2V) which consequently adds to the weight of the predicate device (total weight 690g) contributing to it weighing more than the Venowave VW5 (260g).

A range of safety and performance tests, including both bench and clinical testing has been performed with the Venowave VW5. These tests included:

- Electrical testing
- Gear motor tests
- Drop tests
- Labeling integrity testing
- Final assembly testing
- Random sample testing of each manufactured lot number, and
- Clinical evaluation with relevant patient populations

Based upon these test results, Venowave Inc. believe the Venowave VW5 group of devices to be substantially equivalent to the approved predicate device, the ActiveCare++ System (K060146) without raising any new safety and/or effectiveness issues.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Venowave, Inc.
c/o Mr. David McLean
2546 Burnford Trail
Mississauga L5M 5E3
CANADA

MAR - 7 2008

Re: K073028
VENOWAVE MODELS VW5-6, VW5-10, VW5-20 AND VW5-30
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: January 28, 2008
Received: January 31, 2008

Dear Mr. McLean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

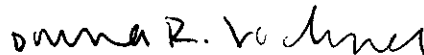
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Venowave Inc.
Traditional 510 (k) Submission

Indications for Use Statement

510(k) Number (if known): K073028

Device Name: Venowave VW5-6, VW5-10, VW5-20, VW5-30

Indications for Use:

- Management of the symptoms of post thrombotic syndrome (PTS)
- Prevention of deep vein thrombosis, (DVT)
- Prevention of primary thrombosis
- Treatment of lymphedema
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- Treatment of leg swelling due to vascular insufficiency
- Treatment of varicose veins
- Treatment of chronic venous insufficiency
- Enhancing blood circulation
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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073028